Title 37

of the

Code of Federal Regulations

July 2012

Patents, Trademarks & Copyrights

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EXHIBIT 9 PAGE 153

Title 37 Code of Federal Regulations

Patents, Trademarks and Copyrights

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> EXHIBIT 9 PAGE 154

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the ex parte with the reply

on behalf of the reexamination requester will be acknowledged or considered. Further, no submissions on behalf of any third parties will be acknowledged or considered unless such submissions are:

- (1) in accordance with §1.510 or §1.535; or
- (2) entered in the patent file prior to the date of the order for ex parte reexamination pursuant to §1.525.
- (h) Submissions by third parties, filed after the date of the order for ex parte reexamination to §1.525, must meet the pursuant requirements of and will be treated in accordance with §1.501(a).

165 FR 76776, Dec. 7, 2000, as amended at 69 FR 56545, Sept. 21, 2004; 72 FR 18905, April 16, 2007]

§ 1.552 Scope of reexamination in ex parte reexamination proceedings.

- (a) Claims in an ex parte reexamination proceeding will be examined on the basis of patents or printed publications and, with respect to subject matter added or deleted in the reexamination proceeding, on the basis of the requirements of 35 U.S.C. 112.
- (b) Claims in an ex parte reexamination proceeding will not be permitted to enlarge the scope of the claims of the patent.
- (c) Issues other than those indicated in paragraphs (a) and (b) of this section will not be resolved in a reexamination proceeding. If such issues are raised by the patent owner or third party requester during a reexamination proceeding, the existence of such issues will be noted by the examiner in the next Office action, in which case the patent owner may consider the advisability of filing a reissue application to have such issues considered and resolved.

[65 FR 76776, Dec. 7, 2000]

§ 1.555 Information material to patentability in ex parte reexamination and inter partes reexamination proceedings.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective reexamination occurs when, at the time a reexamination

pursuant to §1.535, and no further submissions proceeding is being conducted, the Office is aware of and evaluates the teachings of all information material to patentability in a reexamination proceeding. Each individual associated with the patent owner in a reexamination proceeding has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability in a reexamination proceeding. The individuals who have a duty to disclose to the Office all information known to them to be material to patentability in a reexamination proceeding are the patent owner, each attorney or agent who represents the patent owner, and every other individual who is substantively involved on behalf of the patent owner in a reexamination proceeding. The duty to disclose the information exists with respect to each claim pending in the reexamination proceeding until the claim is Information material to cancelled. patentability of a cancelled claim need not be submitted if the information is not material to patentability of any claim remaining under consideration in the reexamination proceeding. The duty to disclose all information known to be material to patentability in a reexamination proceeding is deemed to be satisfied if all information known to be material patentability of any claim in the patent after issuance of the reexamination certificate was cited by the Office or submitted to the Office in an information disclosure statement. However, the duties of candor, good faith, and disclosure have not been complied with if any fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct by, or on behalf of, the patent owner in the reexamination proceeding. Any information disclosure statement must be filed with the items listed in §1.98(a) as applied to individuals associated with the patent owner in a reexamination proceeding, and should be filed within two months of the date of the order for reexamination, or as soon thereafter as possible.

> (b) Under this section, information is material to patentability in a reexamination proceeding when it is not cumulative to information of

reexamination proceeding, and

- (1) It is a patent or printed publication that establishes, by itself or in combination with other patents or printed publications, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the patent owner takes in:
 - Opposing an argument unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability of a claim pending in a reexamination proceeding is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-ofproof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) The responsibility for compliance with this section rests upon the individuals designated in paragraph (a) of this section and no evaluation will be made by the Office in the reexamination proceeding as to compliance with this section. If questions of compliance with this section are raised by the patent owner or the third party requester during a reexamination proceeding, they will be noted as unresolved questions in accordance with §1.552(c).

[57 FR 2036, Jan 17, 1992, as amended at 65 FR 76776, Dec. 7, 2000]

§ 1.560 Interviews in ex parte reexamination proceedings.

(a) Interviews in ex parte reexamination proceedings pending before the Office between examiners and the owners of such patents or their attorneys or agents of record must be conducted in the Office at such times, within Office hours, as the respective examiners may designate. Interviews will not be permitted at any other time or place without the authority of the Director. Interviews for the discussion of the patentability of claims in patents involved in ex parte reexamination proceedings will not be conducted prior to the

record or being made of record in the first official action. Interviews should be advance. Requests arranged in participate reexamination requesters in interviews with examiners will not be granted.

> (b) In every instance of an interview with an examiner in an ex parte reexamination proceeding, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the patent owner. An interview does not remove the necessity for response to Office actions as specified in §1.111. Patent owner's response to an outstanding Office action after the interview does not remove the necessity for filing the written statement. The written statement must be filed as a separate part of a response to an Office action outstanding at the time of the interview, or as a separate paper within one month from the date of the interview, whichever is later.

[65 FR 76777, Dec. 7, 2000]

§ 1.565 Concurrent office proceedings which include an ex parte reexamination proceeding.

- (a) In an ex parte reexamination proceeding before the Office, the patent owner must inform the Office of any prior or concurrent proceedings in which the patent is or was involved such as interferences, reissues, ex parte inter reexaminations, reexaminations, or litigation and the results of such proceedings. See §1.985 for notification of prior or concurrent proceedings in an inter partes reexamination proceeding.
- (b) If a patent in the process of ex parte reexamination is or becomes involved in litigation, the Director shall determine whether or not to suspend the reexamination. See for inter reexamination partes §1.987 proceedings.
- (c) If ex parte reexamination is ordered while a prior ex parte reexamination proceeding is pending and prosecution in the prior ex parte reexamination proceeding has not been terminated, the ex parte reexamination proceedings will usually be merged and result in the issuance and publication of a single certificate under § 1.570. For merger of inter partes reexamination proceedings, see § merger of ex parte 1.989(a). For

reexamination and proceedings, see §

(d) If a reissue a reexamination pro pursuant to § pending concurre will usually be proceedings or to proceedings. Wh application and proceeding examination will with § § 1.171 tl owner will be rec the same claims i the ex parte reex: the pendency of examiner's action owner in a merg both the reissue reexamination] physically entered reexamination p reissue application grant of the reiss reissue applicat reexamination, se (e) If a patent

reexamination is interference, the reexamination Director will not an interference u of this title) to been presented administrative pa filed within ten (administrative motion for susp the administrativ concurrent inter interference of a 165 FR 76776. D FR 50001, Aug.

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16, 2007]

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ase 3:11-cv-01698-DMS-BLM Document 78-5 Filed 05/17/13 PageID.2704 Page 7 of 21

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Aloxandria, Virginia 22313-1450 www.usplo.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/011,430	01/11/2011	7585311		1162
20995	7590 03/28/2011		EXAM	INER
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2040 MAIN FOURTEEN	STREET NTH FLOOR	,	ART UNIT	PAPER NUMBER
IRVINE, C	A 92614			2 2 2
			DATE MAILED: 03/28/201	1

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. B0x1450
Alexandria, VA 22313-1450

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NEW YORK, NY 10036-4003

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. 90/011,430.

PATENT NO. 7585311.

ART UNIT 3993.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

		Control No.	Patent Under Reexamination
	Notice of Intent to Issue	90/011,430	7585311
	Ex Parte Reexamination Certificate	Examiner	Art Unit
		JEANNE M. CLARK	3993
	The MAILING DATE of this communication appears of	n the cover sheet with the co	rrespondence address
1. 🖾	Prosecution on the merits is (or remains) closed in this subject to reopening at the initiative of the Office or up issued in view of (a) Patent owner's communication(s) filed: 24 Feb. (b) Patent owner's late response filed: (c) Patent owner's failure to file an appropriate re (d) Patent owner's failure to timely file an Appeal (e) Other: Status of Ex Parte Reexamination: (f) Change in the Specification: Yes No (g) Change in the Drawing(s): Yes No (h) Status of the Claim(s): (1) Patent claim(s) confirmed: 1-3,5-25 and 28- (2) Patent claim(s) amended (including dependence) (3) Patent claim(s) cancelled: (4) Newly presented claim(s) patentable: (5) Newly presented cancelled claims: (6) Patent claim(s) previously currently	s ex parte reexamination propon petition. Cf. 37 CFR 1.3 bruary 2011. sponse to the Office action Brief (37 CFR 41.31).	oceeding. This proceeding is 13(a). A Certificate will be mailed:
	(7) Patent claim(s) not subject to reexamination	n: <u>4,26, and 27</u> .	180
	Note the attached statement of reasons for patentabil necessary by patent owner regarding reasons for pate to avoid processing delays. Such submission(s) should Patentability and/or Confirmation." Note attached NOTICE OF REFERENCES CITED (P	entability and/or confirmation d be labeled: "Comments C	n must be submitted promptly
Service Services	Note attached LIST OF REFERENCES CITED (PTO/		stitute.).
Die Hermann	The drawing correction request filed on is:		570
	Acknowledgment is made of the priority claim under 3 a) All b) Some* c) None of the certi been received. not been received. been filed in Application No. been filed in reexamination Control No. been received by the International Bures	5 U.S.C. § 119(a)-(d) or (f). fied copies have	ំ ដា
, _	* Certified copies not received:		
	Note attached Examiner's Amendment.		
Same	Note attached Interview Summary (PTO-474).		(4)
э. Ц	Other:		
cc: Re	quester (if third party requester)		

Page 2

Application/Control Number: 90/011,430

Art Unit: 3993

Summary of the Proceedings

A third party requested reexamination of claims 1-25 and 27-30 of U.S. Patent No. 7,585,311 ("the '311 patent") based upon the following proposed rejections supported by alleged substantial new questions of patentability (SNQs):

- 1. Claims 1-4, 8, 22-23, 25, and 27-30 of the '311 Patent are anticipated by U.S. Pat. No. 5,569,306 to Thal ("Thal '306").
- 2. Claims 1-3, 8, 22-25, and 28-30 of the '311 Patent are obvious in view of U.S. Pat. No. 6,585,730 to Foerster ("Foerster") in view of Thal '306.
- 3. Claims 5-8, 11-12, and 14-15 of the '311 Patent are obvious based on Thal '306 in view of U.S. Pat. No. 5,891,168 to Thal ("Thal '168").
- 4. Claims 5-8, 11-12, and 14-15 of the '311 Patent are obvious based on Foerster in view of Thal '306, and further in view of Thal '168.
- 5. Claims 8-10 and 24 of the '311 Patent are obvious based on Thal '306 in view of U.S. Pat. App. Pub. No. 2003/0120309 to Colleran ("Colleran").
- 6. Claims 8-10 and 24 of the '311 Patent are obvious based on Foerster in view of Thal '306, and further in view of Colleran.
- 7. Claim 21 of the '311 Patent is obvious based on Thal '306 in view of U.S. Pat. No. 5,443,482 to Stone ("Stone").
- 8. Claim 21 is obvious based on Foerster in view of Thal '306, and further in view of Stone.
- Claims 13 and 16-20 of the '311 Patent are obvious based on Thal '306 in view of Thal '168 and further in view of U.S. Pat. No. 4,872,840 to Bori ("Bori") and/or "Suturing techniques for periodontal plastic surgery," by Regan L. Moore & Margaret Hill, Periodontology 2000, vol. 11, 1996 ("Moore").
- 10. Claims 13 and 16-20 of the '311 Patent are obvious based on Foerster in view of Thal '306 and Thal '168 and further in view Bori and/or Moore.

An order granting reexamination was mailed on February 6, 2011. The order determined that only Foerster raised a SNQ for claims 1-3, 5-25, and 28-30 because it had teachings relevant to the method step of tensioning the suture to compress an area of tissue to bone after the insertion of the second anchor, which is a limitation added by the May 8, 2009 amendment and

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Application/Control Number: 90/011,430

Art Unit: 3993

identified as the reasons for allowance in the prior examination. See page 21 of the request. See,

also page 13 of the order. On February 24, 2011, the patent owner filed a waiver of the

statement under 37 CFR 1.530. This action addresses the patentability of claims 1-3, 5-25, and

28-30 of the '311 patent. Reexamination was not requested or ordered for claims 4, 26, and 27

of the '311 patent.

STATEMENT OF REASONS FOR PATENTABILITY AND/OR CONFIRMATION

The following is an examiner's statement of reasons for patentability and/or confirmation

of the claims found patentable in this reexamination proceeding:

The prior art of record fails to anticipate or render obvious a method of attaching soft

tissue to bone comprising inserting a first anchor into bone, wherein the first anchor is positioned

underneath the soft tissue such that no part of the anchor extends beyond an edge of the soft

tissue and inserting a second anchor in combination with all the limitations of claim 1.

The third party requester states that Foerster teaches all the limitations of claim 1 except

for inserting a first anchor into the bone and passing a first length of suture from the first anchor,

Thal '306 teaches the missing limitations of claim 1, and that it would be obvious to combine the

teachings to result in the claimed method. See, e.g., pages 31-44 of the request dated January 11,

2011. Therefore, the third party requester concluded that Foerster in view of Thal '306 renders

obvious independent claim 1 and selected dependent claims of the '311 patent.

The examiner respectfully disagrees. Foerster in view of Thal '306 does not render the

claimed method obvious as alleged by the third party requester. Requester states that the claimed

method is nothing more than a combination of known method steps, wherein each step "...

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merely performs the same function as it does separately." See, e.g., page 39 of the request. However, the teachings of Foerster, when viewed as a whole, clearly do not support this conclusion. Foerster clearly discusses methods similar to Thal '306 in the background of the invention section and states the disadvantages of methods like Thal '306 (e.g., eyelet design that stresses the sutures, the high level of skill required to properly perform the procedure, no means for adjusting or measuring suture tension) that his method overcomes. See column 2 line 43 to column 4 line 53). It is further submitted that use of a first anchor, like shown in Thal '306, would render Foerster's method inoperable for its intended purpose. Foerster's method requires that the first length of suture be directly attached to the soft tissue in order to draw the soft issue towards the anchor (see, e.g., column 5 lines 26-28). If the first length of suture was connected to a first anchor in the bone beneath the soft tissue, as taught by Thal '306, Foerster's method would not accomplish its goals because the first length of suture merely passes through the soft tissue, and therefore, would not be able to draw the soft tissue towards the anchor. In addition, Foerster's method, as modified by Thal '306, would be incapable of adjusting or measuring suture tension because the first length of suture is attached to a bone anchor and not the soft tissue. Therefore, the tension placed on the soft tissue could not be measured or felt by the surgeon, which is a disadvantage that Foerster sought to overcome. For these reasons, the examiner disagrees with third party requester that the combination of Foerster and Thal '306 would predictably result in the method of claim 1. In summary, Foerster in view of Thal '306 fails to render obvious the method of claim 1 and dependent claims 2, 3, 5-25, and 28-30 of the '311 patent.

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The other references of record (Thal '168, Colleran, Stone, Bori/Moore) will not be specifically addressed because the request did not advanced that these references raise a substantial new question of patentability, or applied these references to the limitations of claim 1.

Any comments considered necessary by PATENT OWNER regarding the above statement must be submitted promptly to avoid processing delays. Such submission by the patent owner should be labeled: "Comments on Statement of Reasons for Patentability and/or Confirmation" and will be placed in the reexamination file.

Conclusion

By EFS: Registered users may submit via the electronic filing system EFS-Web, at

https://sportal.uspto.gov/authenticate/authenticateuserlocalepf.html.

By Mail to: Mail Stop Ex Parte Reexam

Central Reexamination Unit Commissioner for Patents

United States Patent & Trademark Office

P.O. Box 1450

Alexandria, VA 22313-1450

By FAX to: (571) 273-9900

Central Reexamination Unit

By hand:

Customer Service Window

Randolph Building 401 Dulany Street Alexandria, VA 22314

For EFS-Web transmissions, 37 CFR 1.8(a)(1)(i) (C) and (ii) states that correspondence (except for a request for reexamination and a corrected or replacement request for reexamination) will be considered timely filed if (a) it is transmitted via the Office's electronic filing system in accordance with 37 CFR 1.6(a)(4), and (b) includes a certificate of transmission for each piece of correspondence stating the date of transmission, which is prior to the expiration of the set period of time in the Office action.

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Any inquiry concerning this communication or earlier communications from the Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:

/Jeanne M Clark/

Jeanne M. Clark

CRU Examiner

GAU 3993

(571) 272-7714

Conferee

Conferee DR

Docket No.: KFX.003RX Customer No. 20995

INFORMATION DISCLOSURE STATEMENT

pplicant

Michael L. Green, et al.

Reexam.

90/011430

No.

Filed

January 11, 2011

For

SYSTEM AND METHOD FOR

ATTACHING SOFT TISSUE TO

BONE

Examiner

Clark, Jeanne Marie

Art Unit

3993

Conf No.

1162

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified re-examination is a PTO/SB/08 Equivalent listing 3 references, of which 3 are enclosed/submitted.

This Information Disclosure Statement is being filed "within two (2) months of the date of the order for reexamination" pursuant to 37 C.F.R. § 1.555. Thus, this submission is timely filed, and no fee is required. Nonetheless, if the Patent Office determines that a fee is required, the Commissioner is authorized to charge any such required fees to Deposit Account No. 11-1410.

Enclosed and listed on the PTO/SB/08 is a Statement of Tate Scott. If the Examiner requires any further information regarding the contents this statement, she is invited to contact the undersigned or request such information pursuant to 37 C.F.R. § 1.105.

Case 3:11-cv-01698-DMS-BLM Document 78-5 Filed 05/17/13 PageID.2714 Page 17 of 21

Application No.:

90/011430

Filing Date:

January 11, 2011

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: _ 4-12-11

Ryan E. Melnick

Registration No. 58,621

Attorney of Record

Customer No. 20995

(858) 836-9000

11016647/adk/040611

Case 3:11-cv-01698-DMS-BLM Document 78-5 Filed 05/17/13 PageID.2715 Page 18 of 21

PTO/SB/08 Equivalent

		1 TO/OB/00 Equivalent
	Application No.	90/011430
INFORMATION DISCLOSURE	Filing Date	January 11, 2011
STATEMENT BY APPLICANT	First Named Inventor	Michael L. Green, et al.
STATEMENT BY APPLICANT	Art Unit	3993
(Multiple sheets used when necessary)	Examiner	Clark, Jeanne Marie
SHEET 1 OF 1	Attorney Docket No.	KFX.003RX

U.S. PATENT DOCUMENTS					
	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear

			FOREIGN PATE	NT DOCUMENTS		
Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T ¹

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹	
	1	Mazzocca et al., "Arthroscopic Single-Row Versus Double-Row Suture Anchor Rotator Cuff Repair," The American Journal of Sports Medicine, 33:1861 (2005).		
-	2	Mazzocca et al., Arthroscopic Single versus Double Row Suture Anchor Rotator Cuff Repair, abstract of presentation made on June 25, 2004 at 2004 Annual Meeting of the American Orthopaedic Society for Sports Medicine in Quebec, Canada, publication date unknown.		
	3	Statement of Tate Scott, dated April 12, 2011.		

11016104/adk/040611

Examiner Signature

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Docket No.: KFX.003RX Customer No. 20995

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant

Michael L. Green, et al.

Re-exam.

90/011430

No.

Filed

: January 11, 2011

For

SYSTEM AND METHOD FOR

ATTACHING SOFT TISSUE TO

BONE

Examiner

Clark, Jeanne Marie

Art Unit

3993

Conf No.

1162

STATEMENT OF TATE SCOTT

Commissioner of Patent P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

I, Tate Scott, declare and state that:

- I am CEO of KFx Medical Corp., the assignee of U.S. Patent No. 7,585,311 upon which the above-identified re-examination is based.
- 2. An Information Disclosure Statement was filed on January 30, 2007 in the application that issued as U.S. Patent No. 7,585,311. That Information Disclosure Statement included as item #147 an article authored by Peter Millett et al., entitled "Mattress double anchor footprint repair: a novel, arthroscopic rotator cuff repair technique," *Arthroscopy: The Journal of Arthroscopic and Related Surgery*, 20(8):875-879 (2004).
- 3. An Information Disclosure Statement is being filed herewith in the above-identified re-examination that includes an abstract of which Peter Millett is a co-author (Mazzocca et al., Arthroscopic Single versus Double Row Suture Anchor Rotator Cuff Repair, abstract of presentation made on June 25, 2004 at 2004 Annual Meeting of the American Orthopaedic Society for Sports Medicine in Quebec, Canada, publication date unknown) and another article of which Peter Millett is a co-author (Mazzocca et al., "Arthroscopic Single-Row Versus Double-

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Application No.: 90

90/011430

Filing Date:

January 11, 2011

Row Suture Anchor Rotator Cuff Repair," *The American Journal of Sports Medicine*, 33:1861 (2005)).

- 4. I had a conversation with Peter Millett during which he told me that the procedures referenced in the 2004 article had been performed in the two years preceding publication of the article.
- He also confirmed that all of the procedures were performed by tying knots as described in the 2004 article.
- 6. I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the above-identified application and any patents issuing thereon.

Date: Apr. 1 12,2011

Tata Scott

to late Scott